European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 March 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
RENVELA

International Nonproprietary Name (INN): ***sevelamer (carbonate)***

On 19 March 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Renvela, 800mg film-coated tablets and 1.6 and 2.4 g powder for oral suspension, intended for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Renvelais also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l. The applicant for this medicinal product is Genzyme Europe B.V.

The active substance of Renvela, sevelamer carbonate, is classified pharmacologically as a phosphate binder (ATC Code: V03AE02). It contains multiple amines separated by one carbon from the polymer backbone. These amines become partially protonated in the intestine and interact with phosphate ions through ionic and hydrogen bonding. By binding phosphate in the gastrointestinal tract, sevelamer lowers the phosphate concentration in the serum. Sevelamer decreases the incidence of hypercalcaemic episodes as compared to patients using calcium based phosphate binders alone, probably because the product itself does not contain calcium.

The benefits with Renvelaare its phosphate-lowering effect for controlling hyperphosphataemia in adult patients on dialysis and in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l. The most common side effects are nausea, vomiting, upper abdominal pain, constipation (very common) and diarrhoea, dyspepsia, flatulence, abdominal pain (common).

A pharmacovigilance plan for Renvela, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “Renvela is indicated for the control of hyperphosphataemia in adult patients receiving haemodialysis or peritoneal dialysis. Renvela is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus $\geq$ 1.78 mmol/l”.
Renvela should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D_3 or one of its analogues to control the development of renal bone disease.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Renvela and therefore recommends the granting of the marketing authorisation.